IN THE SPECIFICATION:

Please amend paragraphs [0002], [0003], [0006], [0012], [0015], [0016], [0019], [0020], [0021], [0024], [0027], [0030], [0032], [0033], and [0035] of the specification as follows:

[0002] Medical imaging is used extensively to diagnose and treat patients. A number of modalities are well known, such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Positron Emission Tomography (PET), and Single Photon Emission Computed Tomography (SPECT). These modalities provide complementary diagnostic information. For example, PET and SPECT scans illustrate functional aspects of the organ or region being examined and allow metabolic measurements, but delineate the body structure relatively poorly. On the other hand, CT and MRI images provide excellent structural information about the body, but provide little functional information.

[0003] PET and SPECT are classified as "nuclear medicine~~,~~" because they measure the emission of a radioactive material which has been injected into a patient. After the radioactive material, e.g., a radiopharmaceutical, is injected, it is absorbed by the blood or a particular organ of interest. The patient is then moved into the PET or SPECT detector which measures the emission of the radiopharmaceutical and creates an image from the characteristics of the detected emission.

[0006] In response to the growing practice of using nuclear medicine imaging, such as PET, many hospitals have built their own radiopharmaceutical manufacturing facilities. This option is also typically very expensive~~,~~; however, due to certain requirements of the facility, such as the structure required to support the massive cyclotron, the air circulation system for the facility which cannot return air into the hospital space, and the shielding requirements arising from the radioactive nature of the radiopharmaceutical. Some hospitals have built separate structures to house radiopharmaceutical production. However, this option, while generally easier to achieve than converting existing hospital space, still requires extensive planning to satisfy all the structural, functional, legal, and regulatory requirements placed on radiopharmaceutical

manufacturing facilities.

[0012] FIG. 3 is a drawing of the synthesis unit of FIG. 2 along with supporting apparatus according to an exemplary embodiment of the invention.

[0015] The manufacturing facility 100 is designed to be transportable. For example, according to one embodiment, the outer dimensions of the manufacturing facility 100 are approximately 14 feet by 60 feet (4.27 meters by 18.29 meters), which allows the manufacturing facility 100 to be shipped by truck or rail to its destination. The manufacturing facility may be equipped prior to shipment with equipment for producing, processing, and packaging a radioisotope ~~radio isotope~~ or radiopharmaceutical, with the exception of the cyclotron 112 which is typically shipped separately due to its large mass. The manufacturing facility 100 ~~110~~ can be installed at a desired site by executing a small number of steps. According to one embodiment, a concrete slab for supporting the manufacturing facility 100 is poured at the desired site, the manufacturing facility is shipped to the site and placed on the slab, the cyclotron 112 is shipped to the site, placed in the manufacturing facility 100 and enclosed within the manufacturing facility, and utilities, including a power source, are connected to the manufacturing facility 100.

[0016] The manufacturing facility 100 may also be equipped with a communications port allowing communication over a network between a remote user and equipment within the manufacturing facility 100. For example, a remote user may conduct remote monitoring and diagnostics of the equipment by communicating with one or more computers 135 ~~104~~ within the manufacturing facility 100 and/or with one or more sensors located on the equipment within the manufacturing facility 100.

[0019] When the ~~they~~ hydrogen or deuterium ions reach the outer rim of the chamber, they are transformed to protons or deutrons and then deflected toward one or more targets, which are typically in the form of a liquid or gas. As the targets are hit by the beam of high energy particles, the target liquid or gas is transformed into a short half life radioactive substance. In the field of PET, the radioactive substance emits positrons and is commonly referred to as a PET

tracer. One common example of a PET tracer is $^{18}F^{-}$. Other examples include ^{13}N, ^{11}C, and ^{15}O. ^{13}N ammonia can be used in blood flow studies of the heart. ^{15}O water may be used in blood ~~blow~~ flow studies of the heart and brain. ^{11}C carbon may be labeled onto many types of biological compounds and used as a tracer to follow the compound through the body or individual metabolic pathway.

[0020] The cyclotron 112 can be oriented vertically, i.e., the plane of the spiral path of the particles is vertical ~~verical~~. The vertical orientation reduces the cross sectional area of the cyclotron on the floor of the manufacturing facility 100, which allows the size, e.g., the width, of the manufacturing facility to be reduced, thus facilitating transportability. An example of a vertically oriented cyclotron which is suitable for use in conjunction with various embodiments of the present invention is the MINITRACE ~~MINItrace~~ cyclotron available from GE Medical Systems. The GE MINITRACE ~~MINItrace~~ cyclotron can be installed in a structure having a relatively narrow width, e.g., 14 feet. Other types of cyclotrons may be used, e.g., horizontally oriented cyclotrons.

[0021] The cyclotron may be housed in its own self shielding housing which includes lead or other shielding for protecting users from exposure to radiation such as gamma rays and neutrons. For example, the GE ~~MINItrace~~ MINITRACE cyclotron is typically housed in a structure which includes a lead, concrete, and boronated plastic shield. The manufacturing facility 100 can be designed to accommodate such a cyclotron which includes its own shield. In addition, the manufacturing facility 100 may include a radioactive shield of its own. For example, as shown in FIG. 1, the walls of the cyclotron room 110 may be equipped prior to transport with a shield 114, e.g., a 2-inch lead shield, which further protects users from radiation. Alternatively, the shielding provided with the cyclotron 112 may be sufficient, such that the walls of the manufacturing facility 100 are not shielded.

[0024] In many applications, the radioisotope produced by the cyclotron 112 is subjected to further processing before being administered to a patient. For example, ^{18}F is commonly converted to ^{18}FDG (2-[^{18}F]-fluoro-2-deoxyglucose), a radiopharmaceutical administered to

patients undergoing PET imaging. To provide this capability, the manufacturing facility may be equipped with a synthesis unit 132, as shown in FIGS. 1 and 2. Prior to synthesis, the radioisotope ~~radio isotope~~ produced by the cyclotron, e.g., $^{18}F^-$, is transferred, e.g., automatically, to a reservoir on the synthesis unit 132.

[0027] Step 3 is nucleophilic substitution. In this step the FDG-precursor 1,3,4,6-tetra-O-acetyl-2-O-trifluoromethanesulphonyl-b-D-mannopyranose (dissolved in acetonitrile) is added to the reaction vessel. The triflate anion (triflouromethanesulphonate) in C2-position is substituted under the presence of a transfer catalyst, such as the KRYPTOFIX ~~Kryptofix~~ 222® catalyst, by F^-. The reaction, shown in FIG. 4, takes place under 85° C. for 5 min.

[0030] Step 5 is a chromatographic purification step. To separate the 2-[^{18}F]FDG from organic by-products, Na^+-anions, KRYPTOFIX ~~Kryptofix~~ 222® catalyst, and remaining [^{18}F]F^- anions after hydrolysis the solution, diluted with sterile water, is pushed through a purification column. The FDG is formulated as an isotonic solution of NaCl.

[0032] The synthesis process may be controlled by a computer 135 ~~104~~ and displayed graphically on a screen along with relevant conditions and values. The components of the synthesis unit 132, e.g., valves, heaters, coolers, etc., can be controlled automatically or manually. Automated synthesis units are commercially available. One example is the TRACERLAB ~~TRACERLab~~ Fx$_{FDG}$ synthesis unit ~~system~~ available from GE Medical Systems. Another example is the TRACERLAB ~~TRACERLab~~ MX FDG synthesis unit ~~system~~ available from GE Medical Systems. Synthesis units are available commercially for producing other radiopharmaceuticals, such as the TRACERLAB ~~TRACERLab~~ FX$_{FDOPA}$ synthesis unit for producing F-labeled dopamine, the TRACERLAB ~~TRACERLab~~ FX$_N$ synthesis unit for producing various types of nucleophilic ~~Nucleophilic~~ substitution produced compounds, the TRACERLAB ~~TRACERLab~~ FX$_E$ synthesis unit for producing various types of electrophilic ~~Electrophilic~~ substitution produced compounds, and the TRACERLAB ~~TRACERLab~~ FX$_C$ synthesis unit for producing various types of ^{11}C labeled compounds.

[0033] FIG. 2 shows an example of a synthesis unit 132 which may be used to manufacture the radiopharmaceutical ^{18}FDG. The synthesis unit 132 includes an ^{18}F separation cartridge 134, a target water vial 136, an $H_2{}^{18}O$ vial 138, a reactor 140, an FDG collection vessel 142, an FDG purification column 144, a reactor needle 146, and a reagent vial 148. FIG. 3 shows the synthesis unit 132 along with supporting apparatuses, including an electronics unit 133, a computer 135, a printer 137, a dewar 139, a vacuum pump 141, a transformer 143, and inert gas and compressed air regulators 145.

[0035] The manufacturing facility 100 may include quality control equipment to measure the quality of the products produced in the facility. For example, GM-tubes may be provided to monitor the activity amounts of the target water of the cyclotron 112, the reactor vessel 140 of the synthesis unit 132, and the radiopharmaceutical collecting vial 142. High performance liquid chromatography equipment with a radioactive detector (Radio-HPLC) or radio-thin layer chromatography equipment (Radio-~~TLD~~TLC) can be provided to measure the radiochemistry purity. High performance liquid chromatography (HPLC) equipment and gas chromatography (GC) equipment can be provided to analyze the chemical purity of the products. The products may also be tested for bacterial pyrogens according to conventional methods and transferred into biological media and incubated for a desired period, e.g., 14 days, to test for sterility.